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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/512,124	08/26/2005	Genhong Cheng	02307K-154600US	8432
20350 7590 08/26/2010 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER DANG, IAN D	
			ART UNIT 1647	PAPER NUMBER
			MAIL DATE 08/26/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/512,124	Applicant(s) CHENG ET AL.	
	Examiner IAN DANG	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,20 and 25-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,20 and 25-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/18/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 18 June 2010 has been entered in full. Claims 1-4, 6-19, 21-24 have been cancelled.

Claims 5, 20, 25-31 are under examination.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 06/18/2010 has been considered by the Examiner.

Rejection Maintained

Claim Rejections - 35 USC § 112, First paragraph (Enablement)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 20, 25-31 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for **a method for reducing viral infection and replication of the Murid herpesvirus 68 (MHV68) in a cell *in vitro* and *in vivo***, does not reasonably provide enablement for a method for inhibiting viral infection and viral replication in a cell *in vitro* or *in vivo* or a method of inhibiting a viral infection in a human. The specification does not

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enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

At page 4 of the response, Applicants argue that alternative mechanisms for inducing the innate immune response likely account for the findings relied upon by the Examiner and the cited evidence is indirect and not at all a reliable predictor of the variability of the effect of poly I:C on viral infections and replication *in vivo* or *in vitro*.

In addition, Applicants provide direct evidence shows the claimed subject matter is broadly enabled as it is being broadly practiced right now without any undue experimentation and subsequent to the Applicants' teachings, a great deal of corroboratory art has been published which evidences that the claimed method does work across a wide spectrum of both subjects and viral species.

Applicants' arguments and response has been considered but are found partially persuasive. Although the references provided by Applicants have provided direct evidence for a decrease in viral infection and viral replication comprising contacting a cell with an effective amount of poly I:C across a broad diversity of species over a diverse collection of viruses, the cited references do not provide any support for the inhibition of viral infection and viral replication by poly I:C. For instance, the reference by Julander (cited in the IDS filed 06/18/2010) provided by Applicants teaches the following:

Treatment of WEEV infection

Pre-treatment with interferon alfacon-1 or Ampligen® 4 h prior to virus challenge resulted in 100% survival of infected animals. Weight gain was observed in infected animals treated with either interferon alfacon-1 or Ampligen®; this was similar to weight gain in sham-infected controls (Table 2). There was no sign of toxicity in drug-treatment groups as measured by weight loss and mortality, and all sham-infected toxicity controls appeared healthy and gained weight.

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There was a highly Significant ($P < 0.001$) reduction in day 4 brain virus titer in animals treated with interferon alfacon-1, where virus was reduced to below the limits of detection (Table 2). Ampligen® was also effective in significantly ($P < 0.01$) reducing virus titer in the brain, although virus was detected in 3 out of 5 animals with a mean titer of $4.3 \pm 1.3 \log_{10}$ CCID_{50/g} tissue (Table 2). The mean brain virus titer in placebo-treated, infected controls was $8.1 \pm 1.8 \log_{10}$ CCID_{50/g} tissue.

The reference by Julander teaches that poly I:C (Ampligen) reduces virus titer in the brain but does not inhibit viral infection.

As disclosed in the previous office actions (see page 9 of the office action mailed 05.30/2008, page 5 of the office action mailed 03/04/2009, pages 3-4 of the office action mailed 02/18/2010), the term “inhibiting” has been interpreted by the Examiner as meaning that an activity will not occur, i.e. viral infection and viral replication in a cell will not occur. Although the art and the specification do not provide any support or working examples for the complete inhibition or viral infection and viral replication as interpreted by the Examiner, the art and specification provide support and working examples for a reduction in viral infection and viral replication.

The recitation of method for reducing a viral infection or viral replication would overcome the enablement rejection.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Examiner Dang
Art Unit 1647
August 18, 2010

/Robert Landsman/
Primary Examiner, Art Unit 1647